9.0 510(k) Summary

NOV 3 0 2001

510(k) Summary
(As required by 21 C.F.R. § 807.92)

K011479

Submitted By:

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Contact Person:

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Date Summary Prepared:

May 10, 2001

Device Names:

(A) ONE TOUCH® FastTake® Blood Glucose Monitoring System
(B) ONE TOUCH® Ultra™ Blood Glucose Monitoring System

Classification Names:

(A) ONE TOUCH® FastTake® Blood Glucose Monitoring System, as per K001427:

- FastTake Compact Blood Glucose Meter and FastTake Test Strips are Class II devices (75 CGA, 21 CFR § 862.1345)
- FastTake Control Solution is a Class I device (75 JJX, 21 CFR § 862.1660)
- Penlet Plus Adjustable Blood Sampler and sterile lancets are Class I devices (79 FMK, 21 CFR § 878.4800)

(B) ONE TOUCH® Ultra™ Blood Glucose Monitoring System, as per K002134:

- Ultra Blood Glucose Meter and Ultra Test Strips are Class II devices (75 CGA, 21 CFR § 862.1345)
- Ultra Control Solution is a class 1 device (75 JJX, 21 CFR § 862.1660)
- Penlet Plus and Ultra Soft Adjustable Depth Lancing Device are Class I devices (79 FMK, 21 CFR § 878.4800).

Substantial Equivalence:

The devices referenced in this submission are substantially equivalent to the previously cleared predicate devices (K001427 and K002134).

Description of Change:

The change addressed in this submission is to the labeling of each product. The modification is the addition of a labeling precaution regarding testing glucose levels from blood collected from sites other than the fingertip.

Statement of Intended Use:	The modified devices have the same intended use as their legally marketed predicates. They are used for the quantitative measurement of glucose in fresh capillary whole blood. The ONE TOUCH® FastTake® Blood Glucose Monitoring System and the ONE TOUCH® Ultra™ Blood Glucose Monitoring System are intended for use outside the body (in vitro diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.
Technological Characteristics:	The modified devices have the same technological characteristics as their legally marketed predicates.
Summary of Performance Data:	As the modification addressed by this submission is applied solely to product labeling, no internal performance data was generated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol A. Adiletto, M.S.
Director of Clinical & Regulatory Affairs
Inverness Medical Technology, Inc.
51 Sawyer Road
Waltham, MA 02453

JAN 17 2002

Re: k011479
Trade/Device Name: LifeScan ONE TOUCH® FastTake® Blood Glucose Monitoring System
LifeScan ONE TOUCH® Ultra™ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA, NBW
Dated: November 15, 2001
Received: November 16, 2001

Dear Ms. Adiletto:

This letter corrects the substantially equivalent letter dated November 30, 2001, regarding the omission of product code NBW for the over the counter Blood Glucose test system.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.1 ODE Indications for Use Statement – ONE TOUCH® FastTake®

Indications for Use Statement

510(k) Number: K011479

Device Name: LifeScan ONE TOUCH® FastTake® Blood Glucose Monitoring System

Indications for Use:

The ONE TOUCH® FastTake® Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The ONE TOUCH® FastTake® System is intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011479

Prescription Use _____ **OR** Over-the-Counter Use ✓
(Per 21 CFR 801.109)

3.2 ODE Indications for Use Statement – ONE TOUCH® Ultra™

Indications for Use Statement

510(k) Number: K011479

Device Name: LifeScan ONE TOUCH® Ultra™ Blood Glucose Monitoring System

Indications for Use:

The ONE TOUCH® Ultra™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The ONE TOUCH® Ultra™ System is intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011479

Prescription Use _____ **OR** Over-the-Counter Use ✓
(Per 21 CFR 801.109)